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510(k) Summary
807.92(c)

SPONSOR **807.92(a)(1)**

Company Name:	inomed Medizintechnik GmbH
Company Address	Im Hausgruen 29 79312 Emmendingen, Germany
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Summary Preparation Date: August 24, 2011

DEVICE NAME **807.92(a)(2)**

Trade Name:	C2 NerveMonitor System
Common/Usual Name:	Nerve Stimulator/Monitor
Classification Name:	Evoked Response Electrical Stimulator
Regulation Number:	21 CFR 882.1870
Product Code:	GWF, ETN
Device Class:	Class II

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

Company	***Product***	***510(k) #***
Medtronic Xomed	Nerve Integrity Monitor 3.0	K083124
Magstim	Nerve Avalanche Thyroid/EMG Motor Nerve Monitor	K083242
Magstim	Neurosign 400 Motor Nerve Monitor	K991583
Medtronic Xomed	Xomed Ball-Tip Monopolar Stimulation probe	K992869
Magstim	Neurosign 800. 8 Channel Motor Nerve Monitor with accessories	K980148
Magstim	Neurosign 800 Motor Motor Nerve Monitor with accessories	K964869

DEVICE DESCRIPTION **807.92(a)(4)**

The C2 NerveMonitor System is a multi-channel intraoperative neurophysiological monitor capable of connecting various styles of patient monitoring electrodes and supplying stimulus for evoked responses. The EMG activity monitoring console uses both video and audio output.

Responses monitored with the device may originate from operator applied stimulus or from direct or indirect mechanical stimulus occurring during the course of surgery.

The following probes and electrodes include a metal tip, an insulated elastic shaft and a protected electrical pin connector to attach them to the NerveMonitor:

Type	Description
522610	Microfork probe
522603	Bipolar concentric stimulation probe
522605	Bipolar BCS stimulation probe, bayonet
525603	Monopolar MS probe length 4.5cm angled
525608	Monopolar MS probe flexible
530626	2 SDN electrodes
530627	SDN electrode
530666	Electrode 15 mm bipolar

DEVICE INTENDED USE **807.92(a)(5)**

The C2 NerveMonitor System is intended for intra-operative monitoring and stimulation for localization and identification of cranial and peripheral motor and mixed motor sensory nerves during surgery, including spinal cord and spinal nerve roots. The C2 NerveMonitor device with the integrated user interface is only allowed for the surveillance, documentation and functional test of motor nerves. It can be used as an additional helping tool during surgical procedures for diagnostic issues. Its basic functions are similar to those of an EMG diagnostic device

Indications for C2 NerveMonitor System Monitoring Procedures include:

Intracranial, Extracranial, Intratemporal, Extratemporal, Neck Dissections, Thoracic Surgeries, and Upper and Lower Extremities.

Indications for C2 NerveMonitor System monitoring of Spinal procedures include:

Degenerative Treatments, Pedicle Screw Procedures, Fusion Cages, Rhizotomy, Orthopedic Surgery, Open and Percutaneous Lumbar and Cervical Surgical Procedures and Thoracic Surgical Procedures.

The system is not intended for monitoring life preserving functions.

The system may not be used for diagnosing brain death.

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COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

Device	Predicate Device Nerve Integrity Monitor 3.0	Predicate Device Neurosign Avalanche Thyroid/EMG Motor Nerve Monitor	Predicate Device Neurosign 400 Motor Nerve Monitor	Subject Device C2 NerveMonitor System
Manufacturer	Medtronic Xomed	Magstim	Magstim	inomed Medizintechnik GmbH
510(k) Number	K083124	K083242	K991583	N/A
Device Class	II	II	II	II
Product code	ETN, GWF	ETN	ETN	GWF, ETN
Description	NIM 3.0 is a multi-channel intraoperative neurophysiological monitor capable of connecting various styles of patient monitoring electrodes and supplying electrical stimulus for evoked responses.	Motor Nerve Monitor, based upon standard computer components, running Windows XP embedded operating system; information is provided to the surgeon via a waveform graph of EMG activity, and audio amplification of this signal so that the surgeon hears this as he/she is operating	Motor Nerve Monitor, based upon proprietary hardware and software; information is provided to the surgeon via a waveform graph of EMG activity, and audio amplification of this signal so that the surgeon hears this as he/she is operating	C2 is a multi-channel intraoperative neurophysiologic al monitor capable of connecting various styles of patient monitoring electrodes and supplying electrical stimulus for evoked responses.
Intended Use	The NIM 3.0 is intended for locating and identifying cranial and peripheral motor and mixed motor-sensory nerves during surgery, including spinal cord and spinalnerve roots. The APS electrode is an accessory intended for providing automatic periodic stimulation to nerves when used with the Medtronic Nerve Monitoring Systems.	Intra-operative monitoring and stimulation of cranial and peripheral motor nerves	Intra-operative monitoring and stimulation of cranial and peripheral motor nerves	The C2 is intended for intra-operative monitoring and stimulation for localization and identification of cranial and peripheral motor and mixed motor sensory nerves during surgery, including spinal cord and spinal nerve roots. The system can provide an automatic periodic stimulation of nerves.

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Device	Predicate Device Nerve Integrity Monitor 3.0	Predicate Device Neurosign Avalanche Thyroid/EMG Motor Nerve Monitor	Predicate Device Neurosign 400 Motor Nerve Monitor	Subject Device C2 NerveMonitor System with accessories
Hardware (main unit)	unknown	Standard PC components	Proprietary microprocessor design	Standard PC components
Headbox Bandwidth Signal Gain	4/8 Channel 15Hz – 1,85kHz ± 3db unknown	2/4 Channel 8Hz – 8kHz ± 3dB 500	4 Channel 10Hz – 5kHz ± 3dB 477	4/8 Channel 0.5Hz – 5kHz ± 3dB, 1-1000
Software	unknown	Windows XP Embedded	C++ proprietary code	Windows XP Embedded
Screen	Touch screen 256Hx256W	15" colour touch screen	6" electroluminescent display	8,4" LCD display
Method of control	Touch Screen	Touch screen – all controls via software except power ON/OFF	Controls via dedicated buttons or via software using menus selected using front-panel buttons	Front-panel dedicated soft keys, rotary knobs
Manner of Stimulation	Electrical stimulation via a probe	Electrical stimulation via a probe	Electrical stimulation via a probe	Electrical stimulation via a probe
Stimulation Range	0.01mA – 30mA	0.05mA – 10mA	0.05mA – 5mA	0.01mA - 25mA
Stimulation Type	Monophasic, square pulse, duration 50-250µs	Square wave, negative edge, 200µs pulse width, constant current	Square wave, negative edge, 200µs pulse width, selectable from 100 to 500µs, constant current, constant voltage	Monophasic, square pulse, negative edge, duration 200µs, constant current
Stimulation Frequency	1Hz, 4Hz, 7Hz, 10Hz	3 or 30Hz	3 or 30Hz	1 - 30Hz
Stimulation Probes	Monopolar, bipolar	Monopolar, bipolar, concentric	Monopolar, bipolar, concentric	Monopolar, bipolar, concentric
Electrodes	Cranial and peripheral motor and mixed-motor-sensory monitoring	Laryngeal electrode; needle electrodes	Laryngeal electrode; needle electrodes	Cranial and peripheral motor and mixed-motor-sensory monitoring
Training Required for Use	Yes; both for surgeon and OR staff	Yes; both for surgeon and OR staff	Yes; both for surgeon and OR staff	Yes; both for surgeon and OR staff
Display and Storage	Waveform Signals displayed on screen, Storage on USB Storage Device	Waveform signals displayed on screen; stimulated responses may be optionally automatically	Waveform signals displayed on screen; individual screens may be stored in non-volatile memory	Waveform signals displayed on screen; individual screens may be stored in non-volatile memory; Storage on USB Storage Device

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		recorded to disc		
Print Capacity	Waveform data can be printed to a external printer	Waveform data and patient information can be printed using the internal thermal printer or via an external Letter sized inkjet printer for the generation of reports using stored data and annotated comments	Waveform data can be printed to a proprietary external thermal printer	Waveform data can be printed on an external printer
Power	100-240V 50/60Hz	110/230V 50/60Hz	110/230V 50/60Hz	100-240V 50/60Hz
Electrical Safety	EN 60601-1, Type BF, Class I	EN60601-1; Type BF, Class I	EN60601-1; Type BF, Class I	EN 60601-1; Type BF, Class I
Compliance Standards	CE-Mark	CE Mark; EN ISO 13485	CE Mark; BS EN 9001; EN ISO 13485	CE Mark, EN ISO 13485

Accessories: Probes

Device	**Predicate Device** Nerve Integrity Monitor 3.0 with accessories	**Predicate Device** Neurosign Avalanche Thyroid/EMG Motor Nerve Monitor with accessories	**Predicate Device** Neurosign 400/800 Motor Nerve Monitor with accessories	**Subject Device** C2 NerveMonitor System with accessories
Manufacturer	Medtronic Xomed	Magstim	Magstim	inomed Medizintechnik GmbH
510(k) Number	K083124, K992869	K083242	K991583, K980148, K964869	N/A
Device Class	II	II	II	II
Product code	ETN, GWF	ETN	ETN	GWF, ETN
Probe	82-25401, 82-25100	3600-00, 3602-00	3600-00, 3602-00	522610, 522603, 522605, 525603, 525608
Manner of Stimulation	Electrical stimulation via a probe	Electrical stimulation via a probe	Electrical stimulation via a probe	
Stimulation Range	0.01mA – 30mA	0.05mA – 10mA	0.05mA – 5mA	0.01mA - 25mA
Stimulation Type	Monophasic, square pulse, duration 50-250µs	Square wave, negative edge, 200µs pulse width, constant current	Square wave, negative edge, 200µs pulse width, selectable from 100 to 500µs, constant current, constant voltage	Monophasic, square pulse, negative edge, duration 200µs, constant current
Stimulation Frequency	1Hz, 4Hz, 7Hz, 10Hz	3 or 30Hz	3 or 30Hz	1 - 30Hz
Stimulation Probes	monopolar, bipolar	monopolar, bipolar, concentric	monopolar, bipolar, concentric	bipolar, concentric
Probe design	- tool holder - touch proof	-tool holder -touch proof connectors	-tool holder -touch proof	- tool holder - touch proof

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Device	Predicate Device Nerve Integrity Monitor 3.0 with accessories	Predicate Device Neurosign Avalanche Thyroid/EMG Motor Nerve Monitor with accessories	Predicate Device Neurosign 400/800 Motor Nerve Monitor with accessories	Subject Device C2 NerveMonitor System with accessories
	connectors - cable assembly	- cable assembly	connectors - cable assembly	connectors - cable assembly
Probe Dimensions	- types: 1 / 64 mm electrode length - types: 0.6/1.1 mm diameter	- 100 mm electrode length - types: 0.4/0.6 mm tip diameter	- 100 mm electrode length - types: 0.4/0.6 mm tip diameter	- types: 1/45/85/130 mm electrode length - types: 0.4/0.5/0.65/1.4 mm diameter -angled
Tip Geometry	- fork electrode, round tip, angled bayonet type	- hemispherical tip, bull's eye electrode, straight, blunt tip	-hemispherical tip, bull's eye electrode, straight, blunt tip	- fork electrode, hemispherical tip, bull's eye electrode, straight, blunt tip round tip, angled bayonet type, straight, blunt tip
Patient contacting material	- stainless steel	- stainless steel	- stainless steel	- stainless steel
Insulation Material	Polypropylene	Polypropylene	Polypropylene	Polypropylene
Electrical Insulation	Electrical insulation on all surfaces not intended to provide electrical contact with the patient	Electrical insulation on all surfaces not intended to provide electrical contact with the patient	Electrical insulation on all surfaces not intended to provide electrical contact with the patient	Electrical insulation on all surfaces not intended to provide electrical contact with the patient

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Accessories: Electrodes

Device	Predicate Device Nerve Integrity Monitor 3.0 with accessories	Predicate Device Neurosign Avalanche Thyroid/EMG Motor Nerve Monitor with accessories	Predicate Device Neurosign 400/800 Motor Nerve Monitor with accessories	Subject Device C2 NerveMonitor System with accessories
Manufacturer	Medtronic Xomed	Magstim	Magstim	inomed Medizintechnik GmbH
510(k) Number	-	K083242	K991583, K980148, K964869	N/A
Device Class	-	II	II	II
Product code	-	ETN	ETN	GWF, ETN
Electrodes	-	1699-00, 1705-00	1699-00, 1705-00	530626, 530627, 530666
510(k) Number	-	K083242	K991583, K980148, K964869	To be defined
Electrode type	-	needle electrodes	needle electrodes	needle electrodes
Electrode design	-	- tool holder -touch proof connectors - cable assembly	- tool holder -touch proof connectors - cable assembly	-PP tool holder -touch proof connectors - cable assembly
Probe Dimensions	-	- needle 20 mm - 0.45 mm diameter	- needle 20 mm - 0.45 mm diameter	- needle 15/20 mm - 0.45/5 mm diameter - handle 20 mm
Geometry	-	- straight, needle tip	- straight, needle tip	- straight, 45° angled electrode, ground electrode straight, needle tip
Patient contacting material	-	- stainless steel	- stainless steel	- stainless steel
Insulation Material	-	Polypropylene	Polypropylene	Polypropylene
Electrical insulation	-	Electrical insulation on all surfaces not intended to provide electrical contact with the patient	Electrical insulation on all surfaces not intended to provide electrical contact with the patient	Electrical insulation on all surfaces not intended to provide electrical contact with the patient

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NONCLINICAL AND CLINICAL TEST **807.92(b)**

SAFETY and EFFECTIVENESS

Preclinical testing verified the design of this device and that all specified requirements were fulfilled. The C2 NerveMonitor and all corresponding accessories are similar in their risks and benefits, as well as their manner of performance, to the predicate devices listed.

CONCLUSION **807.92(b)(3)**

The C2 NerveMonitor System with accessories are similar to the predicate devices in part or in whole in:

- intended use, .
- materials and
- technological characteristics

The C2 NerveMonitor System introduces no new questions concerning safety and efficacy.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Inomed Medizintechnik GMBH
c/o Mr. Saschka Busch
IM Hausgruen 29
Emmendingen
Germany 79312

OCT - 6 2011

Re: K111647
Trade/Device Name: C2 NerveMonitor System
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF, ETN
Dated: August 30, 2011
Received: September 2, 2011

Dear Mr. Busch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K111647

Device Name: C2 NerveMonitor System with accessories

Indications for Use:

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Indications for C2 NerveMonitor System monitoring of Spinal procedures include:

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The system is not intended for monitoring life preserving functions.

The system may not be used for diagnosing brain death.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K111647

Prescription Use X
(Per 21 CFR 801.109)